formed on them only by qualified veterinarians, or under their direct supervision. This would certainly eliminate the possibility of an unqualified person ear cropping or otherwise mutilating a pet, and would help protect the interests of the animal and the veterinarian alike.

The Public Governance of Science and Research Animal Welfare

T.E. Malone

The following is excerpted from a speech given by Dr. Thomas E. Malone, Deputy Director of the National Institutes of Health, at the 26th Annual Meeting of the American Association of Laboratory Animal Scientists (AALAS), Anaheim, California, October 5, 1977.

I trace the expression "The Public Governance of Science" to a Columbia University bicentennial lecture given by Dr. Donald Fredrickson, Director of the National Institutes of Health (NIH), in December 1976. In that lecture he said that as recently as a quarter of a century ago, when NIH and AALAS were emerging, "there were no formal arrangements for setting a social priority to the scientific question one hoped to answer." The proprieties, he went on to say, were largely covered by the Hippocratic Oath, and except for rules on the use of radioactive isotopes, there were few regulations involving ethical considerations. There was a certain autonomy in the scientific imperative, and scant attention — save through the responsibility and self-governance of individual scientists — was given in a collective sense to animal welfare, the use of human subjects in research, biohazards, other legal and ethical considerations that accompany the research effort, and indeed, the selection of research problems and priorities bearing on the well-being of the American public.

There is a hazy and somewhat sequential pathway that one can follow to provide some insight into the reasons for the absence of public intervention in biomedical research until relatively recent times. Before World War II, the federal government was involved in peacetime research, primarily as an adjunct to its limited public health activities. There were, of course, important gains in research of cholera and other infectious and dietary deficiency diseases, but, by and large, the private sector provided the preponderant support for biomedical research. There was not very much in the way of "public patronage" of science, and so the public did not have to be overly concerned about how its monies were being spent.

As discussed by Stephen Strickland in his book entitled *Politics, Science and Dread Disease* (1972), "a bill to secure government support in the search for a cure for cancer was introduced in Congress in 1927 by the senior Senator from West Virginia, Matthew M. Neeley. Mr. Neeley's bill would have provided a $5 million reward 'to the first person who discovered a practical and successful cure

for cancer'." Despite the fact that the bill did not pass, he did receive thousands of letters from individuals who claimed to possess infallible cancer cures.

The basic beginnings of a federal biomedical research effort were nonetheless emerging. In 1930, the Congress (in the Ransdell Act) created the National Institute of Health, authorized the construction of two buildings, created a fellowship program, and in a separate piece of legislation established a Division of Mental Hygiene in the Public Health Service to investigate mental and nervous diseases. Again through Congressional action, the National Cancer Institute was established in 1937. This was the first in a series of mandates to create the categorical, disease-oriented Institutes that now make up most of the NIH.

Biomedical research sustained its greatest period of growth in the two decades following World War II, due to a convergence of several circumstances. Under the research program of the Office of Scientific Research and Development during the war years, there were well-known successes in atomic energy, the wonder drugs and electronics. The war itself brought into prominent display the wonders of science and technology. The orbiting of Sputnik by the Soviet Union in 1957 provided another powerful stimulus for enhancing our nation's technological capabilities. The U.S. commitment to scientific progress was fervent and unquestioning, and biomedical science was a beneficiary of this national spirit. Appropriations at the NIH steadily climbed, and decisions on where to put the emphasis in research were left largely to the scientific community itself, which fortunately carried out this trust with uncompromising excellence.

This state of affairs existed until the mid-sixties, when the roof caved in. A period of diminishing support for biomedical research began. There were competing pressures, from the conflict in Southeast Asia to the plight of the urban poor. Funding for biomedical research reached a plateau, then declined, and was elevated only by a variety of new legislative initiatives that began to set research policies for the NIH. The National Cancer Act of 1971 served as the prototype, and we now find that more than 60% of the NIH budget is associated with targeted, special emphasis programs. This is a manifestation of the increasing interest the "public" had begun to show in the choice of problems made by the research community, assessing them in terms of their apparent relevance to specific disease problems. At the urging of various groups interested in a number of diseases, Congress established the National Cancer Program, and created Commissions, Boards, and Panels to review the conduct and support of biomedical research in such disease areas as diabetes, arthritis, epilepsy, and Huntington's chorea. The mood of the sixties generated examination and close public scrutiny of new legal, ethical and social imperatives in biomedical research.

Part of the public's current concern is due to the high cost of today's sophisticated and complex research, and its expectation that the scientific community will assume greater responsibility for the effects of research on the quality and cost of health care. The adoption of a system of national health insurance will undoubtedly increase the public's appetite for effective new diagnostic and treatment approaches, and for improved medical care. This in turn will escalate pressures to make the most effective use of the research dollar.

Central to the public's increasing involvement is its realization of the ascending power of science — the control of fertility; the means for the determination of fetal fitness; the means for abnormal extensions of life, and for surrogate

organs; the dramatic possibilities of recombinant DNA research, and the attendant need for social and ethical imperatives.

There are dozens of examples that one could use to show the diversity of processes involved in the engagement of the public in these matters of science. Each has its own origins and evolution. For example the Tuskegee incident catalyzed the development of guidelines for the use of human subjects in research and the creation of a Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *[Ed. Note — The "Tuskegee incident" refers to a long-range study of the progress of untreated syphilis in a population of black men from Macon County, Alabama. The study began in 1932, and was sponsored by the Venereal Diseases Division of the U.S. Public Health Service. The human subjects were divided into three groups: 399 with advanced cases of syphilis which had never been treated, 275 who had received inadequate treatment some years before, and 201 nonsyphilitic controls. Effective treatment was available throughout the 40 year period of the study, but was deliberately withheld in order to investigate the alleged occurences of spontaneous recovery without medication. The study ceased four months after a critical report of its activities appeared in a 1972 edition of* The New York Times.*]* This Commission has issued a number of reports calling for the protection of prisoners, the fetus, and candidates for psychosurgery. Many of these have been translated into regulations. Guidelines for research involving recombinant DNA molecules were the end point of an extraordinary effort at self-regulation on the part of the scientifc community. Broad public participation in assessing these guidelines came later.

Animal Welfare Considerations

Against this background of the explosive development of biomedical research in this country and the lagging, but now vital, participation of the public in its governance, one might ask how well we have done to satisfy ourselves and the public in the area of animal welfare. As we well know, about 60% of all biomedical research today involves the use of animals, and the research community has an absolute obligation to the proper and humane treatment of animals so crucial to the health of the public. Unfortunately, policies relating to this dictum have neither arisen easily, nor yet reached the point of total application.

A prohibition against cruelty to animals was incorporated into the first legal code of the Massachusetts Bay Colony. Article 92 of that Code reads: "No man shall exercise any tyranny or cruelty towards any brute creatures which are usually kept for man's use." The Code went on to state that proper care should be taken of livestock.

Many years later, in 1906, as a result of the widespread publicity over inhumane treatment of cattle being transported across state lines by rail, Congress enacted the so-called "28-hour law." This law required that cattle be rested for four hours after every 24 hours in transit. The U.S. Department of Agriculture (USDA) was given the responsibility for inspecting rest stations. The USDA has remained the regulatory agency for federal animal welfare legislation, although the legislation itself has been broadened to include laboratory and many other nonfarm animals.

Even before the passage of these and other laws, however, scientists were

concerned about animal welfare in research and exercised self-governance in this area. In 1952, an Institute of Laboratory Animal Resources (ILAR) was set up within the National Research Council to disseminate information and educational materials, establish standards and upgrade laboratory animal resources. This was a reflection of the long-standing recognition by the scientific community of the ethical and scientific responsibility to provide humane care for animals used in research. Under a contract from the NIH, ILAR prepared a *Guide for the Care and Use of Laboratory Animals* which has become a primary reference on standards of animal care. More than 200,000 copies of the *Guide* have been distributed since it was first published in 1963.

In 1966 the Laboratory Animal Welfare Act was passed, and its successor was the Animal Welfare Act of 1970. The Act was stimulated by the public outburst of pet owners who feared that their animals might end up in a research laboratory. Standards under the Act are enforced by the USDA in about 3000 research facilities.

Generally speaking, I believe that we would all agree that the American scientific community has fared very well under animal welfare legislation. Researchers have a great deal of freedom to employ animals as they wish in their experiments, and we will keep it this way — *IF* we keep our house in order.

Every so often a cry is heard that the United States should use the approach embodied in England under the British Cruelty to Animals Act of 1876, as amended. Under the Act, animal experiments can be conducted only in a registered lab open to government inspection, individuals must have a license in order to perform an experiment, and each type of animal experiment must be approved.

I believe that former NIH Director, Dr. James Shannon, testifying in 1965, pretty well answered the proponents of that proposal. He said that while he found the British system quite satisfactory when he worked at Cambridge University in the mid-1930's, he could not recommend its adoption in the United States. The magnitude of the U.S. research effort made the highly centralized British system impractical.

I believe that our experience since 1965 has shown that the people of the United States, through the Congress, and we research scientists, through our regulations, have been innovative enough to demonstrate that further legislation is not, at present, needed to correct abuses or prevent unnecessary cruelty to research animals.

But please do not forget that in recent years several new federal animal welfare laws have been passed, reflecting a serious, ongoing effort in behalf of all animals. On balance, these laws have been beneficial. Some of these laws are designed to extend certain humane standards in the transport of animals to the common carriers, mainly the airlines. Humane society findings have shown that dogs and other animals have been shipped in inadequate containers, exposed to extremes of heat and cold, or been otherwise mistreated while in transit. These abuses, while occurring in only a small fraction of animal shipments, are inexcusable and must be corrected.

It is gratifying to note how the research community has accepted the NIH laboratory animal care guidelines which are being used to accredit research facilities and institutions. Accreditation is voluntary, but nearly 400 institutions have obtained it and more are applying. *[Ed. Note — 378 institutions have full accreditation as of December 1979. The American Association for the Accreditation of Laboratory Animal Care will release a current list in the first quarter of 1980.]* A number of NIH facilities has been accredited since 1966. A new edition of the guidelines will cover actual use of animals in the laboratory, in addition to the care and management of such animals. *[Ed. Note — Revised edition of the NIH* Guide *was published January 1, 1979.]*

I am pleased to report to this group that a revised NIH policy on animal welfare will probably be released before the end of this month, after approval by the Public Health Service. *[Ed. Note — Revised policy was approved and released in the* NIH Guide for Grants and Contracts *January 1, 1979.]* It is the result of a fine cooperative effort at NIH among staff in the Office for Protection from Research Risks, the Division of Research Resources, and the Division of Research Services. This policy is more stringent than before and requires a stronger commitment from institutions to comply with the *Guide*. I would like to summarize some of the new requirements appearing for the first time or receiving greater emphasis in this revised policy:

- Institutions must submit to the NIH a written assurance that they are commited to follow the NIH "Principles for the Use of Animals" and the *Guide for the Care and Use of Laboratory Animals*.
- Submission of assurance forms is required every five years.
- Maintenance of five-member institutional committees is required, and for the first time, institutions sponsoring grant applications and contract proposals will have to provide committee members' names and credentials to the NIH. The committee is to oversee the institution's animal facilities and procedures.
- Humane transportation must be provided for animals. In addition, the NIH has amended Form NIH 398 (Information and Instructions for Application for Research Grant) to include a paragraph on "Animal Subjects" in which the applicant must indicate whether animals are involved and give information on the kinds of animals to be used and plans to avoid unnecessary discomfort or injury to the animals.
- Accreditation by the American Association for the Accreditation of Laboratory Animal Care (AAALAC) is considered the best means of demonstrating compliance with provisions of the *Guide*. An alternative to AAALAC accreditation is a review, at least annually, of the animal facilities and procedures by the institution's committee (see above). If not in immediate compliance, an annual report will be required indicating progress toward full compliance. If no attempt is made to correct deficiencies within a responsible time, this could be the basis for withholding awards.

Other cognate actions at the NIH include the following:

- Distribution of the NIH "Principles" to the Division of Research Grants (DRG) Executive Secretaries and study section members.
- The request that DRG Executive Secretaries make a notation on their "pink sheets" if there is concern about the use of animals.

- Inclusion of the NIH "Principles" in ILAR's revision of the *Guide for the Care and Use of Laboratory Animals.*
- Consideration by the NIH Associate Director for Extramural Research and Training of the suggestion that routine examination of animal facilities of large program projects, centers, etc., be built into the NIH peer review process.

Public Awareness and Ethical Issues

As in other areas, there is a fundamental change in public concern for animals in research. The public awareness is shifting from questions of housing, care and feeding of laboratory animals to profound ethical questions about the use of animals in research.

The public is asking tougher questions all the time, and it behooves us to ask the same questions of ourselves — before they are asked of us. Does the potential good justify the use of an animal in an experiment? Will the research yield fruitful results which cannot be obtained by other means? Is the research necessary? Are we prepared to terminate an experiment whenever its continuation may result in unnecessary suffering to an animal? If the answers to these questions are "yes," then I for one have no difficulty in supporting the research. For only through the use of animals can we obtain much of the knowledge we need to provide better health care and longer life.

These questions are addressed directly in our revision of the NIH Manual Chapter 4206, "Care and Use of Animals," to which I referred earlier. I know that most of you involved in institutional animal care programs have looked to the NIH to strengthen your hand here, and we believe that this revision will do just that.

In closing, I should say that I do not fear greater public scrutiny of science and scientists. I believe that scientists are fallible human beings and that they behave best in situations where they know they must be accountable to their peers. In the last analysis, no legal constraint or regulatory authority can so well police scientists as they themselves. Their own standards, their own moral and ethical principles, govern them most effectively.

If scientists demonstrate by their behavior their sure assumption of their responsibilities to the environment within as well as outside their institutions, then science has nothing to fear but much to gain from greater public interest and involvement in scientific endeavors.

There is a basic challenge here to shape research policy so that productivity and excellence are maintained while responsiveness to society's needs and concerns is also assured.